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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,326	04/03/2006	Yusuke Nakamura	082368-003000US	9667

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EXAMINER

GUSSOW, ANNE

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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08/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/526,326		NAKAMURA ET AL.	
	Examiner		Art Unit	
	Anne M. Gussow		1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 4, 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-76 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,8-35 and 37-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/20/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3, 4, 7, 17, 28, 31, 36, 43, 44, and 49 have been amended.

Claim 2 has been cancelled.

Claims 5, 6, 8-35, and 37-76 remain withdrawn.

2. Claims 1, 3, 4, 7 and 36 are under examination.

The examiner has noted that the claim identifier for claim 5 reads "original" but this claim was previously withdrawn.

The examiner acknowledges applicant's request to rejoin Groups I (claim 1) and II (claims 2-4, 7 and 36) of the restriction requirement. Since applicant has cancelled claim 2 and amended claim 1 to be drawn to the limitations of claim 2, applicant's argument is moot.

3. The following Office Action contains NEW GROUNDS of Rejection.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on February 20, 2007 was filed after the mailing date of the first action on the merits on February 1, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

Objections Withdrawn

5. The objection to the drawings has been withdrawn in view of applicant's amended drawing.
6. The objections to the specification have been withdrawn in view of applicant's amendments to the specification.
7. The objection to claim 2 as referring to a non-elected claim is withdrawn in view of applicant's cancellation of claim 2.

Rejections Withdrawn

8. The rejection of claims 2-4 and 7 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "biological activity equivalent" is withdrawn in view of applicant's amendment to the claim.
9. The rejection of claim 7 under 35 U.S.C. 101, as being drawn to non-statutory subject matter is withdrawn in view of applicant's amendment to the claim.
10. The rejection of claims 2-4 and 7 under 35 U.S.C. 102a and 102e as being anticipated by Tang, et al. (WO 02/22660A2) is withdrawn in view of applicant's amendment to the claims.

11. The rejection of claims 2-4, 7, and 36 under 35 U.S.C. 102e as being anticipated by Tang, et al. (WO 02/22660A2) is withdrawn in view of applicant's amendment to the claims.

Response to Arguments and NEW GROUNDS OF REJECTION

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 3-4, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3-4, and 7 are indefinite for reciting the phrase "cell proliferative activity" in claim 1. The phrase "cell proliferative activity" is unclear because a proliferative activity could mean anything from stimulating proliferation to inhibiting it, to having some qualitative role in between. Since applicant has not explicitly defined "cell proliferative activity" in the as-filed specification, the definition of "a cell proliferative activity" is unclear.

14. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1643

The amendment of claim 36 to delete the phrase "one or more nucleic acids selected from the group consisting of CGX 2" renders the claim indefinite because it is not clear from the amended claim what the reagent in the kit is binding to, DNA, RNA, or protein. Applicant is requested to amend the claim to include the limitation "binds to the nucleic acid sequence of CGX2". Should applicant amend the claim to read on binding to the protein, the claim would not read on the invention under examination.

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. The rejection of claims 3-4, 7, and newly amended claim 1, under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response filed May 4, 2007 has been carefully considered but is deemed not to be persuasive. The response states, "the specification teaches an NFXL1 polypeptide can include SEQ ID No. 12 and teaches the particular identified domains within the NFXL1 polypeptide" (see response page 21). In response to this argument, although the claim has been amended to read "95% identity" from substitutions, deletions, and insertions, the specification does not provide guidance regarding which structural domains need to be retained in the protein to maintain the functional activity of the protein. The location of several structural domains have been provided in the specification (see example 4, particularly page 72 lines 7-11) however, there is no accompanying description that would associate the claimed cell proliferative activity of

the protein with one of the specific structural domains identified. Therefore, one of skill in the art would not know which residues of the protein to modify to maintain the cell proliferative functional activity of the protein and have 95% sequence identity to SEQ ID No. 12.

Regarding the polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to the complement of the nucleotide sequence of SEQ ID No. 11, wherein the polypeptide has a cell proliferative activity, again, the specification does not provide guidance regarding which structural domains in the protein need to be retained in the polypeptide to maintain the functional activity of the protein. Therefore, one of skill in the art would not know which residues of the nucleic acid to mutate and still encode a protein with the cell proliferative activity of the CGX2 polypeptide.

17. Claims 1, 3-4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a polynucleotide encoding a polypeptide having at least 95% identity to SEQ ID No. 12. While the amino acid sequence of SEQ ID No. 12 is adequately described in the specification as-filed, thereby providing an adequate basis for the polypeptide of SEQ ID No. 12; there is insufficient written description as to the identity of a polypeptide having at least 95% sequence identity to SEQ ID No. 12 that

would still maintain the function of the polypeptide. Consequently, the specification does not provide an adequate written description of a polynucleotide encoding a polypeptide having at least 95% sequence identity to SEQ ID No. 12.

The specification as filed does not provide adequate written description support for a polynucleotide encoding a polypeptide having at least 95% sequence identity to SEQ ID No. 12. Polypeptides having diverse functions are encompassed by the phrase 95% identity. Thus a broad genus having potentially highly diverse functions is encompassed by the phrase 95% sequence identity and conception cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. For example, Skolnick et al. (Trends in Biotechnology, 2000. Vol. 18 pages 34-39) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., Abstract and Sequence-based approaches to function prediction, page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular Abstract and Box 2). Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Therefore, only SEQ ID No. 12 meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear

Art Unit: 1643

that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed. (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath at page 1116.).

Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications. Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Conclusion

18. No claims are allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1643

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

July 23, 2007



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER